UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

September 22, 2004

Note to Reader

Subject: Specific Issues for Comment – Docket OPP-2004-0033

On September 22, 2004, EPA announced in the *Federal Register* the availability of the Revised Comparative Ecological Risk Assessment and related documents for nine rodenticides. These documents may be obtained from the public docket or through the EPA website. The publication of the *Federal Register* notice opens a 60-day public participation period. During the comment period, stakeholders are encouraged to comment on the Revised Comparative Ecological Risk Assessment (dated July 2004), the document titled "Analysis of Rodenticide Bait Use" (dated September 2, 2004), and/or to provide additional information related to the use and importance of these nine rodenticide products. The Agency recognizes that there are significant public health and other benefits associated with the use of rodenticide baits, and will give careful consideration to those benefits in reaching a risk management decision. Topics upon which EPA would be particularly interested in receiving comment or additional information are discussed below. (Please note that this list is not exhaustive, and EPA will consider any and all comments received.)

Possible Risk Mitigation Measures

The public is encouraged to comment on the content of the risk assessment and related documents, as well as to submit risk management ideas or proposals. Such comments and/or risk mitigation proposals could address ideas about how to manage ecological risks associated with the use of rodenticides while preserving the critical benefits they provide.

Endangered Species Considerations

EPA is working with the United States Fish and Wildlife Service and the National Marine Fisheries Service to further evaluate the potential effects of rodenticides on endangered species. In response to a formal consultation requested by EPA in 1991 under Section 7 of the Endangered Species Act, the

United States Fish and Wildlife Service issued a Biological Opinion in 1993, titled *Effects of 16 Vertebrate Control Agents on Threatened and Endangered Species*. The Biological Opinion included jeopardy determinations for mammals, birds, and reptiles potentially exposed via primary or secondary exposure to brodifacoum, bromadiolone, chlorophacinone, diphacinone, warfarin, bromethalin, zinc phosphide, and cholecalciferol. The species addressed, jeopardy and no-jeopardy determinations, and the Service's reasonable and prudent alternatives and/or measures for each of the eight rodenticides are provided in Attachment E of the Comparative Ecological Risk Assessment.

EPA believes that it may be necessary to reinitiate consultation with the Services to supplement and reevaluate the 1993 Biological Opinion because (1) the original consultation did not include difethialone (which was registered in 1995), (2) additional species have been listed since the previous consultation, and (3) some carcasses of endangered species have been found to contain rodenticide residues.

EPA invites interested parties to comment on the 1993 Biological Opinion, including the jeopardy determinations and the "reasonable and prudent alternatives/measures" to minimize take. In light of comments received, the Agency will consider whether to pursue implementation of the 1993 Biological Opinion as an interim measure in advance of re-consultation with the Services.

Additional Topics for Comment

EPA is interested in obtaining additional information related to topics where data are limited or where more current information may be available. Examples of types of reliable information that would be informative with respect to the uncertainties identified in the risk assessment include the following.

- Additional toxicity data – particularly acute, chronic, and secondary toxicity as well as retention of some active ingredients in the liver, blood, and other body tissues
- Additional data on metabolism and retention times of rodenticides in rodents and nontarget species
- Specific use information by formulation, including typical amounts applied by use site, seasonally, and annually; distances applied from buildings; amounts used in rural versus urban areas; use by Certified Applicators versus homeowners and other non-certified applicators; and other such relevant information
- Information on the number and species of birds and nontarget mammals frequenting baited areas and the likelihood of those animals finding and consuming bait or poisoned primary consumers in the various use areas
- Methods to determine liver concentration(s) and total body burdens of rodenticide that would corroborate death or show whether such a cause-effect relationship is appropriate (e.g., the "threshold of toxicity" concentration)
- Data on the impacts of sublethal effects of rodenticides on reproduction and nontarget mortality (e.g., clotting abnormalities, hemorrhaging, stress factors including environmental stressors, such as adverse weather conditions, food shortages, and predation)

- Data regarding the potential bioaccumulation of repeated sublethal exposures to bait or poisoned rodents utilized as food by predators and scavengers
- Additional incident data

Examples of types of reliable information that would be useful with respect to the Agency's analysis of the use of rodenticides and their associated benefits include the following.

- Prevalence of resistance to baits containing warfarin or any other rodenticide in any target rodent, use site, or geographic area, especially in the United States
- Examples of how resistance to rodenticide baits has been successfully managed
- Examples of successful commensal rodent control programs in urban areas
- Examples of successful integrated pest management (IPM) programs targeting any type of rodent pests
- Amounts of annual use for all nine rodenticide baits addressed in the risk assessment
- Comparative efficacy data for rodenticide baits
- Wholesale and retail price of rodenticide baits
- Relative importance of rodenticide baits relative to nonchemical control methods
- Common zinc phosphide uses, including main target pests and use sites
- Detailed estimates of the types of damage caused by rodents in the United States and the economic loss resulting from such damage

During the public comment period, EPA plans to work with the United States Department of Agriculture, the Centers for Disease Control and Prevention, the United States Fish and Wildlife Service, the National Marine Fisheries Service, the United States Department of Defense, and other interested stakeholders to identify and propose mitigation measures to reduce risks while maintaining the key benefits of the rodenticides. If you wish to participate in this process, please contact the Chemical Review Manager for the Rodenticides: Kelly White at 703-305-8401 or at white.kelly@epa.gov.